II. REMARKS

A. Status of the claims

Claims 8, 20 and 46 have been amended without prejudice to incorporate features recited in original claims 36, 37, 38, and 44. Support for the amendments can be found, e.g., in original claims 36, 37, 38, and 44 and in paragraphs [0108] to [0110] of the specification.

Claims 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38, and 40-49 are pending.

Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Rejection under 35 U.S.C. § 103

Claims 8-11, 13, 14, 16, 20-24, 29, 30, 32-38, and 40-49 were rejected under 35 U.S.C. § 103 (a) over U.S. Patent No. 4,910,205 to Kogan et al. in combination with U.S. Patent No. 5,968,547 to Reder et al.

1. Independent claims have been amended to further patentably differentiate over the combination of the Kogan patent and the Reder patent

Applicants submit that, to advance prosecution of this case, independent claims 8, 20 and 46 have been amended without prejudice in this amendment to recite in pertinent part that, in the presently claimed transdermal delivery system, (i) "a softening agent [is] selected from the group consisting of dodecanol, undecanol, octanol, a glycol, glycanol and a medium-chain triglyceride of the caprylic/capric acids of coconut oil"; and (ii) "a solvent [is] selected from the group consisting of a monoester of a dicarboxylic acid, monomethyl glutarate and monomethyl adipate."

The Kogan patent states that "[e]ssential oils useful in the [invention described therein] … include eucalyptus, spearmint, cedarwood, wintergreen, peppermint and rosemary oils, with rosemary oil being preferred." See the Kogan patent, column 2, lines 1-4.

Applicants submit that essential oils described in the Kogan patent do not read on (i) "a softening agent selected from the group consisting of dodecanol, undecanol, octanol, a glycol, glycanol and a medium-chain triglyceride of the caprylic/capric acids of coconut oil"; and (ii) "a solvent selected from the group consisting of a monoester of a dicarboxylic acid, monomethyl glutarate and monomethyl adipate," as recited in amended claims 8, 20 and 46 of the present application.

Accordingly, Applicants submit that, even if combined (a position which is refuted), the combination of the Kogan patent and the Reder patent would not replicate the claimed invention, as the combination of the reference would necessarily result in a transdermal delivery device which contains an essential oil, an ingredient which is excluded from the scope of the present claims.

2. It is improper to combine the Kogan patent, which is directed to treatment of allergies by administering loratidine, with the Reder patent, which is directed to treatment of pain by administering buprenorphine

In response to the Applicants' argument that it is improper to combine the Kogan patent with the Reder patent, the Examiner stated:

> *It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the cited prior art in the field of applicant's endeavor and Kogan is concerned about transdermal delivery of loratidine and Reder is concerned about transdermal delivery of a drug over 3-5 days following the*

> *pharmacokinetics of the drug that is attained by specific structure and formulation of a transdermal drug delivery system, and their combination is reasonably as stated above.*

Applicants respectfully disagree. Independent claims 1 and 46 recite "[a] method of effectively treating seasonal allergic rhinitus, chronic idiopathic urticaria, or both conditions in a human patient, comprising administering loratadine … by applying a transdermal delivery system containing loratadine or a pharmaceutically acceptable salt thereof to the skin of a patient, and maintaining said transdermal delivery system in contact with the skin of the patient for at least 5 days …" Independent claim 20 recites "a transdermal delivery system containing loratidine." "Loratidine … is a long-acting tricyclic antihistamine … and it is used mainly for treating nasal and non-nasal symptomps of seasonal allergic rhinitis, but may also be used in the treatment of chronic idiopathic urticaria." See the specification, paragraph [0005].

In contrast, the Reder patent is directed to "methods of treating patients with buprenorphine that provide effective analgesic levels of buprenorphine for prolonged periods of time while eliminating or minimizing dependence, tolerance, and side effects, thus providing a safe and effective method of pain management." See the Reder patent, column 2, lines 55-60. "Buprenorphine is an opioid partial agonist and shares may of the actions, such as analgesia, of opioid agonists." See Id., column 8, lines 37-38.

Applicants submit that loratidine, an antihistamine recited in the present claims, is different both structurally and in its effects in the body from buprenorphine, the therapeutic agent of the methods of the Reder patent.

Applicants further submit that "treating seasonal allergic rhinitus, chronic idiopathic urticaria" as recited in the present claims is a different field of endeavor, than "treating pain", which is a focus of the Reder patent.

Accordingly, Applicants submit that the Reder patent, which is directed to methods of treating pain with buprenorphine is neither in the field of applicant's endeavor nor is reasonably pertinent to the particular problem with which the applicant was concerned- "[a] method of effectively treating seasonal allergic rhinitus, chronic idiopathic urticaria, or both conditions in a human patient, comprising administering loratadine ..." as recited in the present claims. Therefore, in accordance with *In re Oetiker, 977 F2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992)*, the Reder patent should not "be relied upon as a basis for rejection of the claimed invention," as it is directed to a divergent field of endeavor.

With regard to the Examiner's statement that "[i]n this case, having available within hands the disclosure of US'205 that teaches loratadine delivered transdermally and US '547 that teaches drug delivery rate over 3-5 days ... one having ordinary skill in the art at the time of the invention would have designed transdermal drug delivery system to deliver loratidine as disclosed by US'205 and use the device disclosed by US '547 and would calculate the transdermal release rates from the available pharmacokinetic data of loratidine to achieve a transdermal delivery device ... that delivers loratidine at a delivery rate in accordance with its pharmacokinetics to treat patients suffering from allergic reactions with great success," Applicants submit that the Examiner has not articulated a rationale of what would have prompted the one having ordinary skill in the art looking to improve on formulations for treatment of allergies (i.e., described in the Kogan patent) to look on a reference concerned with the treatment of pain by administering buprenorphine (i.e., the Reder patent), which is a different field of endeavor. Accordingly, Applicants submit that the Examiner has failed to provide a sufficient rationale to establish a prima facie case of obviousness. See, e.g., MPEP, Section 2142 ("When the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper.").

3. Even if combined (a position which is refuted), the combination of the Kogan patent and the Reder patent would not replicate the claimed invention

a) buprenorphine, the active ingredient of the Reder patent, is excluded from the scope of the present claims

In response to the Applicants' argument that, even if the Kogan patent and the Reder patent were combined (a positioned which is refuted), one skilled in the art would not arrive at the presently claimed invention because independent claims 8, 20 and 46 all recite that the active agent is limited to loratidine and the formulations and methods of the Reder patent all contain buprenorphine as a necessary ingredient, the Examiner stated:

> *Kogan teaches loratidine administered transdermally and it is evident from the disclosure of US '547 that when the drug is included in the described transdermal device, the drug follows and is delivered according to its pharmacokinetics for period of 5 days as desired by applicants. The structure and formulation of the reservoir of the present transdermal device are identical to that of US '547.* (emphasis added).

Applicants respectfully disagree. Independent claims 8, 20 and 46 all recited that the active agent in the transdermal delivery system consists of loratidine. As discussed above, "[l]oratidine … is a long-acting tricyclic antihistamine … and it is used mainly for treating nasal and non-nasal symptomps of seasonal allergic rhinitis, but may also be used in the treatment of chronic idiopathic urticaria." See the specification, paragraph [0005].

In contrast, in the methods and the transdermal delivery system of the Reder patent, the active agent is buprenorphine. See e.g., the Reder patent, column 2, lines 63-67. As discussed above, "[b]uprenorphine is an opioid partial agonist and shares may of the actions, such as analgesia, of opioid agonists." See Id., column 8, lines 37-38.

Applicants submit that loratidine, an antihistamine recited in the present claims, is different both structurally and in its effects in the body from buprenorphine, the only

therapeutic agent utilized in the methods of the Reder patent. Accordingly, Applicants submit that, contrary to the Examiner's assertion, the formulation of the reservoir of transdermal devices of claims 8, 20, and 46, which all contain loratidine, are not identical to the formulations of the Reder patent, which all contain buprenorphine.

Accordingly, Applicants submit that, even if combined (a position which is refuted), the combination of the Kogan patent and the Reder patent would not replicate the claimed invention.

b. the combination of the Kogan patent and the Reder patent does not explicitly teach the specific delivery profile of loratidine as recited in the present claims

As acknowledged by the Examiner, the Kogan patent does not explicitly teach the specific delivery profile of loratidine as recited in the present claims. See, e.g., page 4 of the Office Action.

Applicants submit that the Reder patent also does not teach or suggest the specific release rates of loratidine at specific time points (i.e., 24 hours, 48 hours and 72 hours), as recited in the present claims. Accordingly, Applicants submit that the Reder patent does not cure the deficiencies of the Kogan patent, which, as acknowledged by the Examiner, does not explicitly teach the specific delivery profile of loratidine as recited in the present claims.

Therefore, Applicants submit that the combination of the Kogan patent and the Reder patent, even if combined (a position which is refuted), does not teach or suggest each and every element of the present claims.

For the foregoing reasons, withdrawal of the obviousness rejection over the combination of the Kogan patent and the Reder patent is respectfully requested.

III. CONCLUSION

An early and favorable action is earnestly solicited. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance prosecution of the present application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By:_____
Cary S. Kappel
Reg. No. 36,561

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940